

## **REMARKS**

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following commentary.

### **I. Status of the Claims**

Claim 23 has been amended with support in the original specification, e.g. figure 21A. Claims 6, 22 and 25 have been amended to delete the recitation of “renal failure.” Claims 3, 5, and 7-19 are cancelled without prejudice or disclaimer. Applicants reserve the right to file one or more continuing/divisional application to pursue the subject matter of any cancelled claims.

Because no new matter is introduced, Applicants respectfully request entry of this amendment. Upon entry, claims 1, 2, 4, 6 and 20 -25 will be pending, with claims 20 and 21 allowed.

### **II. Species Election**

Applicants have responded to the species election requirement and elected anti-FGF-23 antibodies that bind to amino acids 25-179 of SEQ ID NO: 1, such as antibodies produced by hybridomas with accession numbers 7838 and 8268, for initial examination on the merits. In this action, the examiner has indicated that claims 1, 2, 4, and 6, which read on non-elected species, are withdrawn (action, page 2, section 2).

In contrast to a restriction requirement, the administrative expediency of a species election comprehends the prospect that a reasonable number of additional species, presently “non-elected,” will be considered when a given species within a recited genus is deemed patentable. See MPEP § 809.02(a). Accordingly, the present withdrawal of claims 1, 2, 4 and 6 is premature, pending a disposition pursuant to § 809.02(a) of the MPEP.

### **III. Priority Claim**

The Examiner objected to the priority claim to Japanese Patent Application No. 2001-401689, filed on December 28, 2001. Applicants respectfully traverse the objection.

The present application is a national phase entry of PCT/JP03/00017, filed on January 6, 2003, which is the first business day following the one-year anniversary date from the filing date of the priority application. As evidenced by the accompanying copy of Japanese act and the partial English translation thereof (submitted as Exhibit A), the Japanese Patent Office, which was the Receiving Office of the PCT application, was closed from December 28, 2002 to January 5, 2003. Therefore, the corresponding PCT application was timely filed to benefit from the priority date of Application No. 2001-401689.

Accordingly, the claims in the present application are entitled to priority date of December 28, 2001.

### **IV. Rejection of Claims under 35 U.S.C. § 112, first paragraph**

The Examiner rejected claims 22 and 25 for alleged lack of enablement. Applicants respectfully traverse the rejection.

The Examiner contends that the specification does not enable a skilled artisan to make an FGF-23 antibody for treating “renal failure.” Without acquiescing to the stated basis for the rejection, Applicants choose to delete “renal failure” in the claims at issue in an effort to advance prosecution. Therefore, the rejection should be withdrawn.

### **V. Rejection of Claims under 35 U.S.C. § 102(b)**

The Examiner rejected claims 23-25 for alleged anticipation by WO 01/66596 by Itoh *et al.*, as evidenced by Yu *et al.*, *Endocrinology*, 2005, 146: 4647-656, and Mohammadi *et al.*, *Cytokine Growth Factor Rev.*, 2005, 16: 107-37. Applicants respectfully traverse the rejection.

Specifically, the Examiner contends that Itoh's antibody that is generated against amino acids 1-179 of FGF-23 inherently (i.e., *necessarily*) would compete with the claimed antibody, which binds amino acids 25-179 of FGF-23.

The specification discloses that FGF-23, which is naturally present in human body, has the activity of decreasing phosphate and 1,25 (OH)<sub>2</sub>D concentration in the serum. *See*, for example, page 19, lines 20 and 21. Exhibit B (*J. Clinical Investigation*, 113: 561-568, 2004) shows an increased phosphate and 1,25 (OH)<sub>2</sub>D level in the serum of FGF-23-null mice. *See* figure 3. As the present application depicts in Figure 21A, 2C3B antibody, which is produced by the hybridoma with accession No. FERM BP-7838, neutralizes the activity of FGF-23, thereby increasing phosphate and 1,25 (OH)<sub>2</sub>D concentration. 2C5L antibody, which is produced by the hybridoma with accession No. FERM BP-8268, has the same effects. Further, both 2C3B and 2C5L antibodies neutralize FGF-23 activity in a dose-dependent manner, as evidenced in Exhibit C to this response. By contrast, Itoh does not teach or suggest that antibody against amino acids 1-179 can neutralize FGF-23 activity, as claim 23 prescribes.

Moreover, the antibodies bind to an overlapping region do not necessarily compete with each other. For instance, Example 10 of the present application shows that 2A2B antibody, which binds amino acids 148-163 of FGF-23, does not compete with either 2C3B antibody or 2C5L antibody. Therefore, although Itoh's antibody and the claimed antibody recognize an overlapping region, they do not inherently (or necessarily) compete with each other, as the Examiner contends.

Because the cited reference does not teach each and every aspect to anticipate the invention, Applicants respectfully request withdrawal of the rejection.

#### **VI. Rejection of Claims under 35 U.S.C. § 102 (a)**

The Examiner rejected claims 23-25 for alleged anticipation by WO 02/14504 (published February 21, 2002) by Yamashita *et al.*, as evidenced by US 2004/0082506 by Yamashita *et al.*,

Yu *et al.*, *supra*, Mohammadi *et al.*, *supra*, and Bost *et al.*, *Immunol. Invest.* 1988, 17: 577-586.

Applicants respectfully traverse the rejection.

As discussed in section III of this response, the claims of the present application are entitled to a priority date of December 28, 2001, which precedes the publication date of the PCT application. Therefore, Yamashita is not qualified art under section 102, and the rejection based on Yamashita should be withdrawn.

#### **VII. Provisional Double Patenting Rejection**

The Examiner provisionally rejected claims 23-25 on the ground of nonstatutory obviousness-type double patenting over claims 10 and 12-15 of co-pending U.S. Patent Application No. 10/344,339, in view of Yu *et al.*, Mohammadi *et al.*, and Bost *et al.*.

Because the rejection is provisional, Applicants choose to defer any action until an actual double patenting rejection is made.

#### **VIII. Potential Rejection of Claims under 35 U.S.C. §§ 103 (a)/102(f) or (g), or 102(e)**

The Examiner asserts that claims 23-25 are not patentably distinct from claims 10 and 12-15 of commonly assigned U.S. Patent Application No. 10/344,339 and requires a showing that the inventions were commonly owned at the time the present invention was made.

Section 35 of the Japanese Patent Law rules that an employer is entitled to the rights of its employee's invention by way of an employment contract. In general, a company's regulation requires an employee assign the right of his invention to the employer by signing an agreement to comply with the company's regulations. Copies of the company's regulation and the agreement between the employer and the employee(s) will be provided in a supplemental response to evidence the common ownership.

### CONCLUSIONS

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees, which may be required regarding this application under 37 CFR §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, then Applicants hereby petition for such extension under 37 CFR §1.136 and authorize payment of the relevant fee(s) from the deposit account.

Respectfully submitted,  
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